

REMARKS

The Examiner's Office Action mailed April 15, 2009, which rejected all pending claims, has been reviewed. Reconsideration in view of the following remarks is respectfully requested. Moreover, Applicants have reviewed the Office Action of April 15, 2009, and submit that the following Remarks are responsive to all points raised therein. Applicants believe that currently pending claims 11-17 are now in form for allowance.

Status of Claims

Claims 11-17 are pending in the application. Claims 1-8 and 10 were canceled. New claims 11-17 have been added. Support for new claims 11-17 can be found throughout the specification, including page 1, lines 16-32, and original claims 3-7 and 10. No new matter has been added.

Rejection of Claims 1 and 10 under 35 USC § 102(b)

- I. Rejection of claims 1 and 10 under 35 U.S.C. § 102(b) as anticipated by Miller et al. (US 5,122,377)

Claims 1 and 10 have been canceled; however, for sake of completeness Applicants submit that new claims 11-17 are novel over Miller et al. To anticipate a claim, a single prior art reference must teach each and every element of the claim. Miller et al. do not teach each and every element of independent claims 11 and 17. In particular, Miller et al. do not teach applying the formulation to the coat of the cat, required by both independent claims 11 and 17. Miller et al. also does not teach a formulation that includes enrofloxacin, pradofloxacin, flupirtine, ponazuril, toltrazuril, or any salt thereof, as required by independent claim 17. As such, Applicants submit that claims 11 and 17 are novel over Miller et al. Claims 12-16 depend directly from claim 11 and as such Applicants also submit that claims 12-16 are novel over Miller et al.

Rejection of Claims 1-10 under 35 USC § 103(a)

- I. Rejection of claims 1-2 and 10 under 35 U.S.C. § 103(a) as being unpatentable over an invention in public use in this country, more than one year prior to the date of application for Patent in the United States, read in light of Miller et al.

Claims 1-2 and 10 have been canceled; however, for sake of completeness Applicants submit that new claims 11-17 are patentable over public use hairball remedies in light of Miller et al. The Examiner noted that non-medicated hairball remedies targeted to cats and dogs were in use in the US since at least 2002 and that Hartz had a hairball remedy that was applied to the pet's front paws so that the pet could lick it off readily. The Examiner also noted that Miller et al. teach a composition that can be applied to the paw of an animal, which the animal then takes up orally.

Although it was known to apply non-medicated (Hartz) and medicated (Miller et al) remedies to cats and dogs' paws, there is no teaching or suggestion anywhere that one could modify the application to apply such remedies to a cat's coat as required by the claims of the present invention. Accordingly, the Examiner has made an assumption about what would have allegedly been obvious, absent the benefit of impermissible hindsight provided by the Applicants' own disclosure, that is not supported by any teaching or suggestion of record. Assumptions of this kind cannot support a proper *prima facie* case of obviousness. *Takeda Chem. Indus. Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007) (obviousness cannot be established based on a combination of references absent "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements **in the way the claimed new invention does**") (citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (2007); emphasis added).

As such, Applicants submit that claims 11 and 17 are patentable over public use hairball remedies in light of Miller et al. Claims 12-16 depend directly from claim 11 and as such Applicants also submit that claims 12-16 are patentable over public use hairball remedies in light of Miller et al.

- II. Rejection of Claims 3 and 5 under 35 U.S.C. § 103(a) as being unpatentable over Watts et al. (US 6,191,143) read in light of Miller et al. (US 5,122,377) .

Claims 3 and 5 have been canceled; however, for sake of completeness Applicants submit that new claims 11-17 are patentable over Watts et al. in light of Miller et al. The Examiner notes that Watts et al. teach a method of topically administering an antimicrobial agent, such as enrofloxacin, to mammals. The Examiner also notes that Miller et al. teach a method of inducing an animal to groom itself by applying a composition to its paw. The Examiner then states that it would have been obvious to a person of ordinary skill in the art at the time of the invention to apply a composition containing enrofloxacin or a salt thereof to the coat or skin of the animal which the latter takes up orally, with a reasonable expectation of success.

First, Applicants disagree with the Examiner's overview of Miller et al. Although Miller et al. do teach applying the composition to an animal's paw, it does not teach anywhere in the specification animal grooming. Second, Watts is concerned with topically applying an antimicrobial agent to treat systemic bacterial diseases, i.e., the antimicrobial agent is absorbed through the skin treating the infection. It is not applied to be orally taken up by the animal. One skilled in the art reviewing the Watts reference, specifically looking at treating systemic infections, would not be envisioning oral uptake and would not combine this reference with Miller. Accordingly, the Examiner has made an assumption about what would have allegedly been obvious, absent the benefit of impermissible hindsight provided by the Applicants' own disclosure, that is not supported by any teaching or suggestion of record. Assumptions of this kind cannot support a proper *prima facie* case of obviousness. *Takeda Chem. Indus. Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007) (obviousness cannot be established based on a combination of references absent "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements **in the way the claimed new invention**

does") (citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (2007); emphasis added).

As such, Applicants submit that claims 11 and 17 are patentable over Watts et al. in light of Miller et al. Claims 12-16 depend directly from claim 11 and as such Applicants also submit that claims 12-16 are patentable over Watts et al. in light of Miller et al.

III. Rejection of Claim 4 under 35 U.S.C. 103(a) as being unpatentable over Endler et al. (WO 01/08682) in light of Miller et al.

Claim 4 has been canceled; however, for sake of completeness Applicants submit that new claims 11-17 are patentable over Endler et al. in light of Miller et al. The Examiner notes that Endler et al. teach the administration of flupertine, or its salt, administered orally, for the treatment of pain in cats and dogs. The Examiner also notes that Miller et al. teach applying a composition to an animal's paw which the animal then licks off of its paw. The Examiner then concludes that because both references are in the analogous art and both contemplate oral administration of medication to animals, it would have been obvious to a person of ordinary skill in the art at the time of the invention to apply a pharmaceutical preparation comprising flupertine to an animal's coat which the animal can then take up orally.

Although it was known to apply medicated (Miller et al) remedies to cats and dogs' paws, there is no teaching or suggestion anywhere that one could modify the application to apply such remedies to a cat's coat as required by the claims of the present invention. Accordingly, the Examiner has made an assumption about what would have allegedly been obvious, absent the benefit of impermissible hindsight provided by the Applicants' own disclosure, that is not supported by any teaching or suggestion of record. Assumptions of this kind cannot support a proper prima facie case of obviousness. *Takeda Chem. Indus. Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007) (obviousness cannot be established based on a combination of references absent "a reason that would have prompted a person of ordinary skill in the

relevant field to combine the elements **in the way the claimed new invention does**") (citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (2007); emphasis added).

As such, Applicants submit that claims 11 and 17 are patentable over Endler et al. in light of Miller et al. Claims 12-16 depend directly from claim 11 and as such Applicants also submit that claims 12-16 are patentable over Endler et al. in light of Miller et al.

IV. Rejection of Claim 6 under 35 U.S.C. 103(a) as being unpatentable over Mertin et al. (US 2006/0177414) in light of Miller et al.

Claim 6 has been canceled; however, for sake of completeness Applicants submit that new claims 11-17 are patentable over Mertin et al. in light of Miller et al. The Examiner notes that Mertin et al. teach the use of pradofloxacin, or its salts, administered orally for treatment of animals. The Examiner also notes that Miller et al. teach applying a composition to an animal's paw which the animal then licks off of its paw. The Examiner then concludes that because both references are in the analogous art and both contemplate oral administration of medication to animals, it would have been obvious to a person of ordinary skill in the art at the time of the invention to apply a pharmaceutical preparation comprising pradofloxacin to an animal's coat which the animal can then take up orally.

Although it was known to apply medicated (Miller et al) remedies to cats and dogs' paws, there is no teaching or suggestion anywhere that one could modify the application to apply such remedies to a cat's coat as required by the claims of the present invention. Accordingly, the Examiner has made an assumption about what would have allegedly been obvious, absent the benefit of impermissible hindsight provided by the Applicants' own disclosure, that is not supported by any teaching or suggestion of record. Assumptions of this kind cannot support a proper prima facie case of obviousness. *Takeda Chem. Indus. Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007) (obviousness cannot be established based on a combination of references

absent “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements **in the way the claimed new invention does**”) (citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (2007); emphasis added).

As such, Applicants submit that claims 11 and 17 are patentable over Mertin et al. in light of Miller et al. Claims 12-16 depend directly from claim 11 and as such Applicants also submit that claims 12-16 are patentable over Mertin et al. in light of Miller et al.

- V. Rejection of Claim 7 under 35 U.S.C. 103(a) as being unpatentable over Hundley et al. (US 6,465,460) in light of Miller et al.

Claim 7 has been canceled; however, for sake of completeness Applicants submit that new claims 11-17 are patentable over Hundley et al. in light of Miller et al. The Examiner notes that Hundley et al. teach the use of toltrazuril, or its salts, administered orally for treatment of animals. The Examiner also notes that Miller et al. teach applying a composition to an animal's paw which the animal then licks off of its paw. The Examiner then concludes that because both references are in the analogous art and both contemplate oral administration of medication to animals, it would have been obvious to a person of ordinary skill in the art at the time of the invention to apply a pharmaceutical preparation comprising toltrazuril to an animal's coat which the animal can then take up orally.

Although it was known to apply medicated (Miller et al) remedies to cats and dogs' paws, there is no teaching or suggestion anywhere that one could modify the application to apply such remedies to a cat's coat as required by the claims of the present invention. Accordingly, the Examiner has made an assumption about what would have allegedly been obvious, absent the benefit of impermissible hindsight provided by the Applicants' own disclosure, that is not supported by any teaching or suggestion of record. Assumptions of this kind cannot support a proper prima facie case of obviousness. *Takeda Chem. Indus. Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007)

(obviousness cannot be established based on a combination of references absent "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements **in the way the claimed new invention does**") (citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (2007); emphasis added).

As such, Applicants submit that claims 11 and 17 are patentable over Hundley et al. in light of Miller et al. Claims 12-16 depend directly from claim 11 and as such Applicants also submit that claims 12-16 are patentable over Hundley et al. in light of Miller et al.

- VI. Rejection of Claim 7 and 9 under 35 U.S.C. 103(a) as being unpatentable over De Spiegeler et al. (US 2006/0240049) in light of Miller et al.

Claims 7 and 9 have been canceled; however, for sake of completeness Applicants submit that new claims 11-17 are patentable over De Spiegeler et al. in light of Miller et al. The Examiner notes that De Spiegeler et al. teach the use of toltrazuril or ponazuril, or its salts, administered orally for treatment of animals. The Examiner also notes that Miller et al. teach applying a composition to an animal's paw which the animal then licks off of its paw. The Examiner then concludes that because both references are in the analogous art and both contemplate oral administration of medication to animals, it would have been obvious to a person of ordinary skill in the art at the time of the invention to apply a pharmaceutical preparation comprising toltrazuril or ponazuril to an animal's coat which the animal can then take up orally.

Although it was known to apply medicated (Miller et al) remedies to cats and dogs' paws, there is no teaching or suggestion anywhere that one could modify the application to apply such remedies to a cat's coat as required by the claims of the present invention. Accordingly, the Examiner has made an assumption about what would have allegedly been obvious, absent the benefit of impermissible hindsight provided by the Applicants' own disclosure, that is not supported by any teaching or suggestion of record. Assumptions of this kind

cannot support a proper prima facie case of obviousness. *Takeda Chem. Indus. Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007) (obviousness cannot be established based on a combination of references absent "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements **in the way the claimed new invention does**") (citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (2007); emphasis added).

As such, Applicants submit that claims 11 and 17 are patentable over De Spiegler et al. in light of Miller et al. Claims 12-16 depend directly from claim 11 and as such Applicants also submit that claims 12-16 are patentable over De Spiegler et al. in light of Miller et al.

Conclusion

In view of the above, Applicants respectfully submit that the pending claims are novel and not obvious over the cited references and request withdrawal of all rejections and allowance of the claims.

The Commissioner is hereby authorized to charge any fee deficiency or credit any overpayment in connection with this amendment to Deposit Account No. 50-4260.

Respectfully submitted,
/JESSICA MONACHELLO/
Jessica Monachello
Reg. No. 58,015
BAYER HEALTHCARE LLC
P.O. Box 390
Shawnee Mission, KS 66201
Tel: 913-268-2038
Fax: 913-268-2889